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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/529,555

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Flemming Madsen

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EXAMINER

BERMAN, SUSAN W

ART UNIT

PAPER NUMBER

1796

MAIL DATE

DELIVERY MODE

11/14/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/529,555	Applicant(s) MADSEN ET AL.	
	Examiner /Susan W. Berman/	Art Unit 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Arguments

Applicant's arguments filed 08-27-2007 have been fully considered but they are not persuasive.

Hu et al, as stated in the rejection, disclose polyvinylpyrrolidone, whci is also claimed by applicant. Polyvinylpyrrolidone is inherently a saturated hydrophilic polymer.

Sawhney et al teach that persulfates as well as peroxygen compounds, such as hydrogen peroxide, are suitable initiators in a polymerization method analogous to the method disclosed by Hu et al. Applicant discloses in the "Background of the Invention" that it is known in the art that peroxides may be used as photoinitiators of vinyl polymerization, such as hydrogen peroxide, peroxydisulphate or peroxydiphosphate (page 5, lines 4-12). Applicant also teaches that peroxydisulphate is used equivalently to "persulphate" (page 5, lines 4-5). Applicant also admits that it is known in the art to enhance peroxide initiated polymerization by addition of soluble metal ions (page 6).

Applicant argues that neither Hu et al nor Sawhney et al teach that peroxydisulphate crosslinking agents also act as co-catalyst for the crosslinking reaction. This argument is not persuasive for the following reasons. Sawhney et al clearly teach persulfates function as initiators. The instant claims are drawn to a method comprising preparing an aqueous solution containing a saturated hydrophilic polymer, a crosslinking agent and a water soluble peroxydisulphate and irradiating the solution. Irradiation of a solution comprising the same components disclosed in the prior art would be expected to result in crosslinking and in a crosslinked hydrogel product. There is no comparative evidence of record to show that the prior art crosslinking agent does not act as a co-catalyst for a crosslinking reaction. Furthermore, it is

Art Unit: 1796

not clear how the crosslinking agent can be considered to be a catalyst since it takes part in a crosslinking reaction and would not be expected to be regenerated as a catalyst would. Does applicant intend to recite that the combination of crosslinking agent and water soluble peroxydisulphate affects the rate of the reaction?

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 11 and 21: It is not clear what is meant by the phrase “photoinitiator having a water soluble peroxydisulphate”. Does the photoinitiator contain a peroxydisulphate moiety? Is the photoinitiator a mixture of a photoinitiator and a peroxydisulphate? It is suggested that the phrase be replaced with “photoinitiator comprising a water soluble peroxydisulphate”. With respect to claims 15 and 16, it is not clear what is meant by copolymers of the polymers recited. Does applicant intend to claim copolymers of the monomers from which the polymers were obtained, such as copolymers of vinyl pyrrolidone?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

Art Unit: 1796

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hu et al [US 2001/0044482 A1] in view of Sawhney et al (5,844,016).

Hu et al disclose IPN compositions for forming hydrophilic hydrogel contact lenses comprising polymerizable monomers and crosslinking agent and a soluble hydrophilic IPN agent, such as polyvinylpyrrolidone, a photoinitiator and/or a thermal initiator. The crosslinker is preferably polyethylene glycol dimethacrylate [0044]. Free radical thermal initiators and photoinitiators are taught for use alone or in combination, such as azo and peroxide compounds and phenyl ketone photoinitiators [0047]. Peroxydisulfate initiators are not mentioned.

Sawhney et al teach a polymer gel obtained by photopolymerization of acrylated PEG in the presence of a combination of chemical initiators and photochemical initiators. The chemical initiators disclosed include potassium persulfate, ammonium persulfate, peroxygen compounds such as hydrogen peroxide and redox catalyst with a transition metal (column 5, lines 38, to column 6, line 56). Sawhney et al teach that a very slow redox-catalysed polymerization can be speeded up by including metal ions and by stimulation of a photoinitiator in the solution (column 6, lines 46-52) See Examples 11, 12 and 22. Sawhney et al teach polymerization by irradiation of acrylated PEG in aqueous solution and in the presence of a photoinitiator, an organic peroxide such as hydrogen peroxide, and a ferrous ion. Sawhney et al teach polymerizing monomers to form a surface coating that appears to be a graft polymerization on the surface, such as a tissue surface. Example 10 discloses a solution comprising polyethylene glycol 400 and an acrylated PEG crosslinking monomer.

It would have been obvious to one skilled in the art at the time of the invention to substitute the initiator system taught by Sawhney et al for the initiator system in the method disclosed by Hu et al. Hu et al provide motivation by teaching that peroxide initiators are useful. Sawhney et al provide motivation by teaching persulfates as well as peroxygen compounds such as hydrogen peroxide are suitable initiators in an analogous polymerization method. Sawhney et al also teach that a slow redox-catalysed polymerization can be speeded up by including metal ions and by stimulation of a photoinitiator in the solution in the presence of the metal ions. One skilled in the art at the time of the invention would have been motivated by a reasonable expectation of taking advantage of the benefits of providing an initiator comprising a photoinitiator, an organic peroxide and ferrous ions to speed up the polymerization, as taught by Sawhney et al. With respect to claims 12 and 22, It would have been obvious to one skilled in the art at the time of the invention to employ a mixture of the IPN agents taught by Hu et al in the compositions taught by Hu et al. The reason is that Hu et al teach several different saturated polymeric IPN agents that provide the same function in the disclosed method.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Nzudie et al (6,174,950) disclose a method for polymerizing an aqueous composition comprising a monomer and dispersing polymer in the presence of free radical initiator, such as persulfate, or by irradiation.

Art Unit: 1796

Hubbell et al (6,632,446) disclose compositions for obtaining gels by photopolymerization of acrylates, such as PEG acrylate, using a co-catalyst, such as an amine or potassium persulfate, with a photoinitiator.

Sassi et al (5,883,211) disclose a method for making thermoreversible hydrogels including preparation of graft copolymers, such as grafted polyvinylpyrrolidone in water.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Susan W. Berman/ whose telephone number is 571 272 1067. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571 272 1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SB
11/9/2007

/Susan W Berman/
Primary Examiner
Art Unit 1796

Application/Control Number: 10/529,555

Page 7

Art Unit: 1796